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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,199	12/05/2003	Jan Lewandowski	34968US2	2436
116 7590 11/28/2008 PEARNE & GORDON LLP 1801 EAST 9TH STREET SUITE 1200 CLEVELAND, OH 44114-3108				
EXAMINER				
CHENG, JACQUELINE				
ART UNIT		PAPER NUMBER		
3768				
MAIL DATE		DELIVERY MODE		
11/28/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/729,199

Applicant(s)

LEWANDOWSKI ET AL.

Examiner

JACQUELINE CHENG

Art Unit

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,12 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8,12 and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. **Claim 7** is objected to because it is unclear if the applicant's referral to the diagnostic test is a noun or a verb and therefore if the claim is a method or an apparatus claim. It is suggested the claim preamble be written as "A ~~diagnostic test~~ method for testing for otitis media, comprising:" Appropriate correction is required.
2. **Claim 12** is objected to because "the effusion viscosity" in line 3 of the claim lacks antecedent basis. It is suggested in the second line of the claim the claim be rewritten as "...wherein the presence and viscosity of middle ear effusion..."

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. **Claims 7, 8, 12, 14 and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Brainard, II (US 6,048,320) in view of Takeuchi (*Viscoelastic Properties Of Middle Ear Effusions From Pediatric Otitis Media With Effusion And Their Relation To Gross Appearance*), in view of Greenwood (US 2006/0172734 A1). Brainard, II discloses using an ultrasound probe to detect the presence of middle ear effusion in a human patient (col. 3 line 8-11, col. 8 line 1-2). Although Brainard, II does not disclose measuring the viscosity of the fluid, it is well known that determining the viscosity helps to diagnose if a bacterial infection in the middle ear effusion is present as discussed by Takeuchi. It would therefore be obvious to use Brainard, II to determine the viscosity of middle ear effusion to further the utility of Brainard to obtain a more accurate diagnoses of, not only the presence of an abnormality, but also what type of abnormality it is, especially since it is well known that ultrasound probes are capable determining viscosity of fluid using the pulse echo amplitude such as disclosed by Greenwood (paragraph 0059). Since there are at least three different types of otitis media (such as Purulent Otitis Media, Serous Otitis Media, and Mucoid Otitis Media, see Jung), it would also be obvious to have at least three different values to compare the viscosity value to, to be able to determine which type of disease is present.

6. **Claims 15, 17, and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Brainard, II in view of Takeuchi, in view of Greenwood, further in view of Erikson (US

4,281,550). Brainard discloses using ultrasonic waves, however fails to disclose how the ultrasonic waves are produced. It would therefore be obvious to one skilled in the art at the time of the invention to use any well known method of creating ultrasound waves such as disclosed by Erikson. Erikson teaches uses a curved array which can have a plurality of transducers are operated simultaneously or have a plurality of transducers operated sequentially (col. 5 line 20-30).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. SU 1337052 A to Mareev.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-5596. The examiner can normally be reached on M-F 10:00-6:30.
9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC

/Long V Le/

Supervisory Patent Examiner, Art Unit 3768